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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2 Sheets

Complete if Known

Application Number 10/551,396

Filing Date 03/31/2004

First Named Inventor Meikle, et al.

Group All Unit Unknown Examiner Name Unknown

Attorney Docket Number: MAYO-0008 US1 (128675.00044)

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|---|--------------------------------|---|--|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | |
| | 5 | WO 97/44668 | 11-27-1997 | Meikle, et al. | Entire Application |
| | 6 | WO 00/55632 | 09-21-2000 | Meikle, et al. | Entire Application |
| | 7 | WO 03/106997 | 12-24-2003 | Meikle, et al. | Entire Application |

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¹ Applicant's unique citation designation number (optional). ² See *Kinds of USPTO Patent Documents* at www.uspto.gov or MPEP 201.04.

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| Substitute for form 1449A/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/551,396 |
| (use as many sheets as necessary) | | | | Filing Date | 03/31/2004 |
| Sheet 2 of 2 Sheets | | | | First Named Inventor | Hopwood, et al. |
| | | | | Group Art Unit | Unknown |
| | | | | Examiner Name | Unknown |
| | | | | Attorney Docket Number | MAYO-0008 US1 (128675.00044) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|--|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 8 | CHANG M.H.Y. et al. Saposins A, B, C and D in Plasma of Patients with Lysosomal Storage Disorders. Clinical Chemistry 43: 8 1325 (2000). | | |
| | 9 | MEIKLE, P.J., et al. Diagnosis of Lysosomal Storage Disorders: Evaluation of Lysosome-Associated Membrane Protein LAMP-I as a Diagnostic Marker. Clinical Chemistry 43: 8 1325-1335 (1997). | | |
| | 10 | Meikle PJ, Ranieri E, Ravenscroft EM, Hua CT, Brooks DA, Hopwood JJ. Newborn screening for lysosomal storage disorders. Southeast Asian J Trop Med Public Health. 1999;30 Suppl 2:104-10. | | |
| | 11 | RENLUND, et al. Studies on the Defect Underlying the Lysosomal Storage of Sialic Acid in Salla Disease. The Journal of Clinical Investigation. 77(2):568-74 (Feb. 1986). | | |
| | 12 | UMAPATHYSIVAM, K., J.J. HOPWOOD, P.J. MEIKLE. Determination of acid alpha-glucosidase activity in blood spots as a diagnosis for Pompe Disease, Clin. Chem. 47(8): 1378-1383 (2001). | | |
| | 13 | UMAPATHYSIVAM, K., J.J. HOPWOOD, P.J. MEIKLE, Determination of acid alpha-glucosidase activity Protein: Evaluation as a Screening Marker for Pompe Disease and Other Lysosomal Storage Disorders. Clin. Chem. 46:9 1318-1325 (2000). | | |
| | 14 | WHITFIELD PD, Nelson P, Sharp PC, Bindloss CA, Dean C, Ravenscroft M, Fong BA, Fietz MJ, Hopwood JJ, Meikle PJ. Correlation among genotype, phenotype, and biochemical markers in Gaucher disease: implications for the prediction of disease severity. Mol Genet Metab. 2002 Jan;75(1):46-55. | | |

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